

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 OR 15(d) of  
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 22, 2016

**NewLink Genetics Corporation**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-35342**  
(Commission  
File Number)

**42-1491350**  
(IRS Employer  
Identification No.)

**2503 South Loop Drive**  
**Ames, IA**  
(Address of principal executive offices)

**50010**  
(Zip Code)

Registrant's telephone number, including area code: **(515) 296-5555**

**Not applicable**  
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

## **Section 8 - Other Events**

### **Item 8.01. Other Events.**

On January 22, 2016, NewLink Genetics Corporation (the "Company") announced the presentation of data that describe a combination therapy of indoximod, an IDO pathway inhibitor, plus gemcitabine/nab-paclitaxel, for patients with metastatic pancreatic cancer.

The press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

**Section 9 - Financial Statements and Exhibits**

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release, dated January 22, 2016, entitled "NewLink Genetics Presents Phase 1b Data of Indoximod in Combination with Gemcitabine/Nab-Paclitaxel for Patients with Metastatic Pancreatic Cancer That Show Encouraging Durable Responses with Delayed Pattern"

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: January 22, 2016

### **NewLink Genetics Corporation**

By: /s/ John B. Henneman III  
John B. Henneman III  
Its: Chief Financial Officer

## INDEX TO EXHIBITS

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## **NewLink Genetics Presents Phase 1b Data of Indoximod in Combination with Gemcitabine/Nab-Paclitaxel for Patients with Metastatic Pancreatic Cancer That Show Encouraging Durable Responses with Delayed Pattern**

AMES, Iowa, January 22, 2016 -- NewLink Genetics Corporation (NASDAQ:NLNK), a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, today announce the presentation of data that describe a combination therapy of indoximod, an IDO pathway inhibitor, plus gemcitabine/nab-paclitaxel, for patients with metastatic pancreatic cancer. This combination immunotherapeutic approach was well tolerated and shows encouraging durable responses with a delayed pattern and a 42 percent objective response rate, including one complete response (CR), according to data presented at the 2016 Gastrointestinal Cancers Symposium (ASCO GI) in San Francisco.

“The preliminary overall response rate is certainly promising, but I am particularly intrigued by the pattern of delayed and durable responses potentially suggesting an immune mediated mechanism of action,” said Nathan Bahary, MD, PhD, Associate Professor in the Division of Oncology and Medical Director of the Pancreatic Cancer Program at the University of Pittsburgh Medical Center, and principal investigator of the study.

These data come from the Phase 1b portion of the trial that included 12 patients who were evaluable for a response. To date, this Phase 1/2 trial has enrolled 50 patients, with a target enrollment of 80 patients in the Phase 2 portion.

In the Phase 1b portion of the trial, the combination therapy with indoximod had an objective response rate of 42 percent (5/12), including one CR. The MPACT study, which established gemcitabine/nab-paclitaxel as standard of care for patients with metastatic pancreatic cancer, demonstrated an objective response rate of 23 percent.

“Pancreatic cancer continues to be one of the deadliest of all malignancies with very limited options for the patients. I am delighted to be part of this study with gemcitabine/nab-paclitaxel in combination with the immunomodulatory agent indoximod, targeting the IDO pathway, as this combination approach seems to offer a potential benefit with minimal added toxicity,” said Andrea Wang-Gillam, MD, PhD, Associate Professor of Medicine in the Division of Oncology at Washington University School of Medicine in St. Louis.

These data are being presented today at ASCO GI, during Poster Session B (12:30-2:00PM and 5:30-7:00PM), “Cancers of the Pancreas, Small Bowel, and Hepatobiliary Tract,” correspond to abstract number 452 entitled, “Results of the Phase 1b Portion of a Phase 1/2 trial of the Indoleamine 2,3-dioxygenase Pathway (IDO) Inhibitor Indoximod plus Gemcitabine/Nab-Paclitaxel for the Treatment of Metastatic Pancreas Cancer.”

## About Indoximod

Indoximod is an orally available small molecule that has shown the potential to interfere with multiple targets within the indoleamine 2,3-dioxygenase (IDO) pathway. It is designed to be used in combination with other therapeutic agents to maximize the body's immune response against a range of tumor types. Indoximod is currently in multiple Phase 2 clinical trials for the treatment of patients with breast, prostate, pancreatic, melanoma and brain cancers and in Phase 1 clinical trials for the treatment of pediatric patients with primary malignant brain tumors.

## About NewLink Genetics Corporation

NewLink Genetics is a biopharmaceutical company at the forefront of discovering, developing and commercializing novel immuno-oncology product candidates, including both cellular immunotherapy and checkpoint inhibitor platforms, to improve the lives of patients with cancer. NewLink Genetics' portfolio includes biologic and small molecule immunotherapy product candidates intended to treat a wide range of oncology indications. NewLink Genetics' product candidates are designed to harness multiple components of the immune system to combat cancer without significant incremental toxicity, either as a monotherapy or in combination with other treatment regimens. For more information, please visit <http://www.newlinkgenetics.com>.

## Cautionary Note Regarding Forward-Looking Statements

*This press release contains forward-looking statements of NewLink Genetics that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release are forward-looking statements, within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "target," "potential," "will," "could," "should," "seek" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about NewLink Genetics' financial guidance for 2015 and beyond; enrollment in or results of its clinical trials for product candidates; its timing of release of data from ongoing clinical studies; its plans related to moving additional indications into clinical development; NewLink Genetics' future financial performance, results of operations, cash position and sufficiency of capital resources to fund its operating requirements; and any other statements other than statements of historical fact. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that NewLink Genetics makes due to a number of important factors, including those risks discussed in "Risk Factors" and elsewhere in NewLink Genetics' Annual Report on Form 10-K for the year ended December 31, 2014 and other reports filed with the U.S. Securities and Exchange Commission (SEC). The forward-looking statements in this press release represent NewLink Genetics' views as of the date of this press release. NewLink Genetics anticipates that subsequent events and developments will cause its views to change. However, while it may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing NewLink Genetics' views as of any date subsequent to the date of this press release.*

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